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Comparative precision analysis of Urinary microalbumin on two Cobas c501 chemistry analyzers, separately operated in different shifts

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Abstract *Background*: Instrument to instrument variability or expectation of precision, whether from same manufacturer or of same make and model if operated separately, is also a point of interest in health care system. *Aim*: Since patients' treatments dependent on analytical outcome, with end products, clinical laboratory reports, such administrative and technical components need to be sorted out. *Objectives*: In presented study we examined precision and reproducibility of urinary micro-albumin results analyzed on two same make-model of analyzer Cobas 6000 c501 (Roche Diagnostics-Cobas-Basil), operated separately in different shifts, morning and evening, to evaluate required analytical precision standardization skills of shift-staff. *Results:* Data of female controls (n = 40) showed correlation of 96.93%; whereas that of males (n = 40) as 96.58%; Diabetic hypertensive female patients (n = 40) as 96.27%; whereas diabetic male patients (n = 40) as y = 96.33% depicting standardization, accuracy, precisions and skills of staff, even working in different shifts. *Conclusion*: Urinary microalbumin, is a biomarker of renal dysfunction, more profound in diabetic patients and less reflective in non-diabetics with variability of co-morbid of cardiovascular and metabolic anomalies. Data revealed 95.32% to 96.93% precision and accuracy of analysis among samples from control and diabetic patients

Keywords Urinary microalbumin, standardization, accuracy, precisions

Introduction

One of the early markers of chronic kidney disease (CKD), urinary microalbumin, manifests as microalbuminuria, when excretion reaches 20-200 mg/L [1,2]. It over excretion depicts increased risk of cardiovascular diseases, metabolic abnormalities, with underlying diabetes mellitus (type 2) and probabilities of mortalities, if remained untreated [3-6]. Moreover, direct correlation have been documented in several studies regarding urinary microalbumin concentrations and metabolic disorders [1,6-9]. Furthermore, microalbumin is a well characterized biomarker of renal dysfunction, more profound in diabetic patients and less reflective in non-diabetics with variability of co-morbid of cardiovascular and metabolic anomalies [10]. Effectiveness of urinary microlabumin in mentioned clinical conditions makes it exclusively significant entity in assessing treatment and management and thus requires accuracy, precision, standardization and reproducibility [7-9]. Earlier studies determined and assessed

interfering components, instrument to instrument variability and/or precision, effects of different analytical methods, variable make and models (manufacturers) of analyzers regarding several serum, blood and urinary components [7-11]. Instrument to instrument variability or choice/expectation of precision, whether from same manufacturer or of same make and model if operated separately, is also a point of marked interest in health care system, where patients' treatments dependent on analytical outcome, with end products, clinical laboratory reports. In presented study we examined precision and reproducibility of urinary micro-albumin results analyzed on two same make-model of analyzer Cobas 6000 c501 (Roche Diagnostics-Cobas-Basil), operated separately in different shifts, morning and evening, to evaluate required analytical precision standardization skills of shift-staff.

Materials and Methods

Our laboratory consist of several automated chemistry, Blood gases, and immunochemistry analyzers inclusive of three Cobas 6000 c501, out of which two were designated to analyze urinary microalbumin, among several other parameters. These two c501 were operated by two different sets of trained and skilled staff, in morning and evening shifts, for special (urinary microalbumin, lactate, ammonia, HbAic) and routine chemistry. Forty each of male and female control subjects (aged 29 to 45 yrs) and same numbers in known diabetics with underlying hypertensive were selected for collection of urine and analysis of urinary microlabumin. Samples were collected in sterile bottles for spot urine and analyzed for microlabumin using TINA-QUANT immune-turbidometric method as provided by manufacturer (Roche Diagnostics, Basil). Data was analyzed using SPSS ver 22 (SPSS.USA) via regression (R^2) correlation analysis. Y and X intercept inclusive of R^2 were calculated and presented as plotted data (Figs 1 to 4).

Results

Results are summarized in Figures 1 to 4. Comparative precision analysis was performed for Urinary microalbumin on two Cobas c501, separately operated in different morning and evening shifts using regression estimation and data revealed 95.32% to 96.93% precision and accuracy of analysis. Data of female controls (n = 40) showed Regression R^2 as y = 0.3451x + 3.8406, whereas that of males (n = 40) as y = 0.3306x + 3.9325 R^2 = 0.9658; Diabetic hypertensive female patients (n = 40) as y = 0.9277x + 1.5397 R^2 = 0.9627; whereas diabetic male patients (n = 40) as y = 0.9633x + 0.684 R^2 = 0.9532, depicting standardization, accuracy, precisions and skills of staff, even working in different shifts. Synchronized, precise, accurate and reproducible outcome of urinary microalbumin analysis has been due to standard training regiments, benchmark protocols followings, usage of proper methodologies and quality control markers and supervision by consultants and senior supervisory staff.

Discussion

Recent and past studies not only assessed precision and accuracy of analyzers from different manufactures regarding various biomarkers but also determined the reproducibility of results within same analyzer categories and quality control materials to evaluate standardization and correctness of methods, protocols, skills and related technical and administrative components [7-13]. Several studies compared cross reactivity of lipemic, icteric or hemolysis factors with analytical capabilities of automated analyzers viz Abbott, Roche and Beckman coulter and precision, accuracy of resultant, concluding that such factors needs to be monitored as heterogeneity does exist amongst indices [12]. Microalbumin, specifically, was also assessed, for both conventional (dip-stick) and automated (analyzer) methods, arguing that which one shall considered as gold standard [8,9]. Nonetheless comparison of spot and timed urine collection for the analysis of urinary microalbumin concluded to be necessary in cases of kidney transplanted patients [10]. Cobas series 6000 with analytical chemistry c501 module is used for more than 38 parameters inclusive of microalbumin and assessing, comparison of accuracy and precision goes on by several experts and scientist to determine standardization of methods as done recently for free light chain gamma-globulins to check response to therapy in monoclonal gammapathies patients [11].

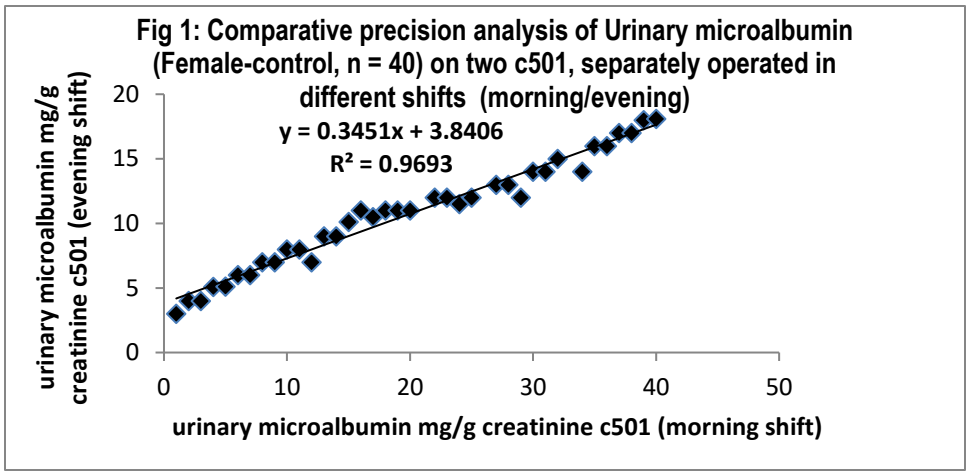


Fig 1: Comparative precision analysis of Urinary microalbumin (Female-control, n = 40) on two c501, separately operated in different shifts (morning/evening)
y = 0.3451x + 3.8406
R² = 0.9693
urinary microalbumin mg/g creatinine c501 (evening shift)
urinary microalbumin mg/g creatinine c501 (morning shift)
0
5
10
15
20
0
10
20
30
40
50

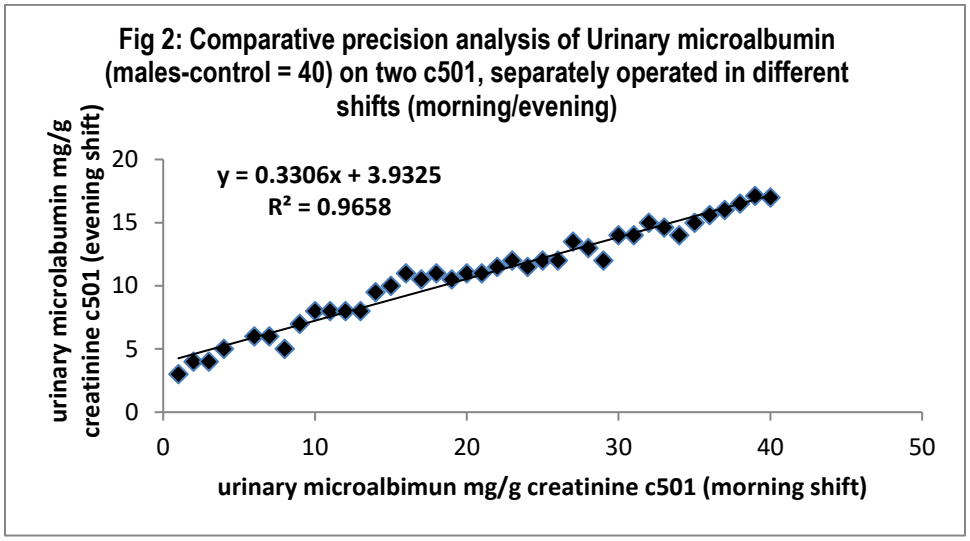


Fig 2: Comparative precision analysis of Urinary microalbumin (males-control = 40) on two c501, separately operated in different shifts (morning/evening)
y = 0.3306x + 3.9325
R² = 0.9658
urinary microlabumin mg/g creatinine c501 (evening shift)
urinary microalbimun mg/g creatinine c501 (morning shift)
0
5
10
15
20
0
10
20
30
40
50

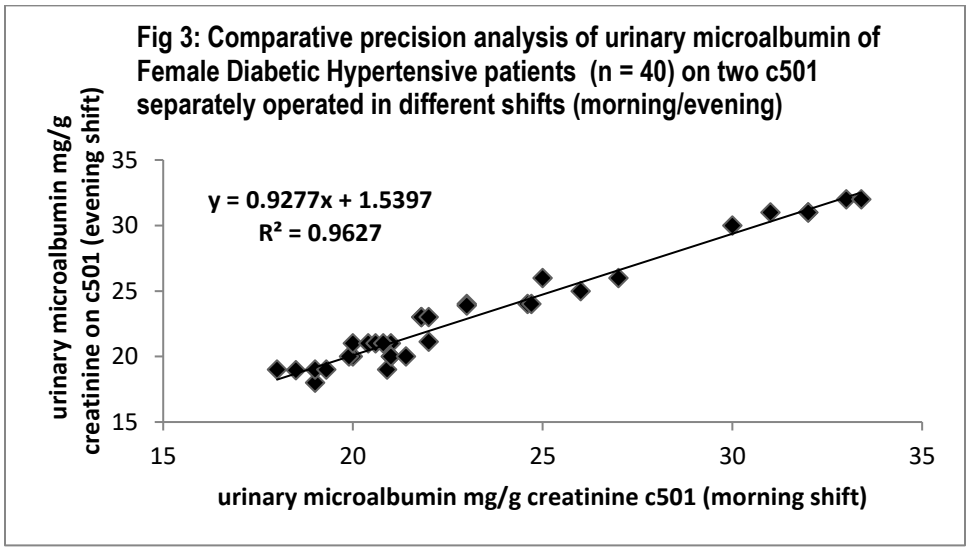
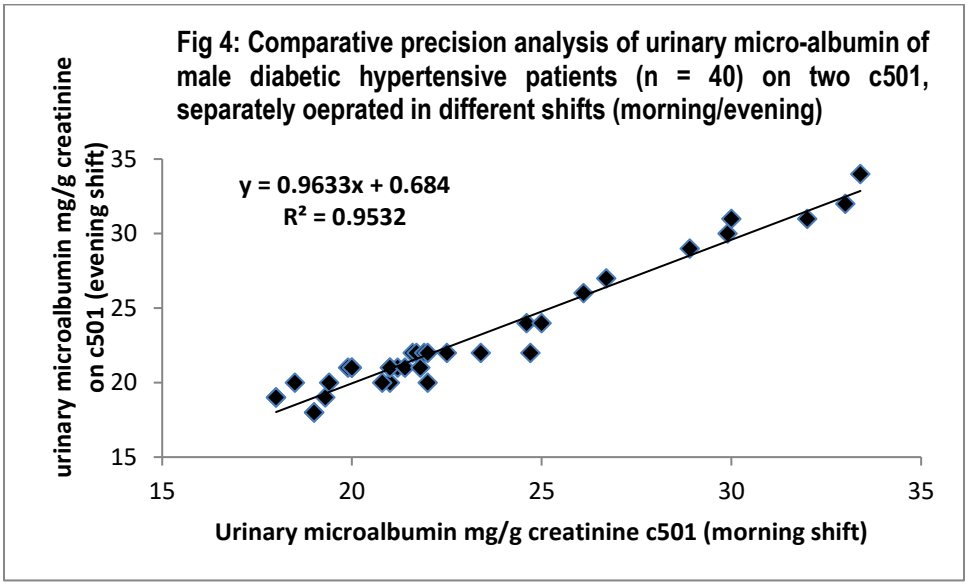


Fig 3: Comparative precision analysis of urinary microalbumin of Female Diabetic Hypertensive patients (n = 40) on two c501 separately operated in different shifts (morning/evening)
y = 0.9277x + 1.5397
R² = 0.9627
urinary microalbumin mg/g creatinine on c501 (evening shift)
urinary microalbumin mg/g creatinine c501 (morning shift)
15
20
25
30
35
15
20
25
30
35



In present study comparative precision analysis was performed for Urinary microalbumin on two Cobas c501, separately operated in different morning and evening shifts using regression estimation and results revealed 95.32% to 96.93% precision and accuracy of analysis. This depicts standardized accuracy, precisions and trained skills of staff, even working in different shifts of morning and evening. Synchronized, precise, accurate and reproducible outcome of lab tests e.g urinary microalbumin analysis, has been an integral part of patient care service of clinical laboratory and requires standard training regiments, benchmark protocols followings, usage of proper methodologies and quality control markers and supervision by consultants and senior supervisory staff. Earlier studies done by our team regarding urinary microlabumin provided detailed data of precisions, accuracy, reproducibility, standard protocols, conventional, modular, standalone analyzers and manual methods [7-9]. Since direct correlation has been established regarding urinary microalbumin concentrations and metabolic disorders [1,6-9], its standard and accurate results are of utmost clinical significance. Urinary microalbumin, as stated earlier, is a well characterized biomarker of renal dysfunction, more profound in diabetic patients and less reflective in non-diabetics with variability of co-morbid of cardiovascular and metabolic anomalies [10].

Conclusion

Present study described comparative precision analysis of Urinary microalbumin on two Cobas c501 chemistry analyzers, separately operated in different shifts. Urinary microalbumin, is a biomarker of renal dysfunction, more profound in diabetic patients and less reflective in non-diabetics with variability of co-morbid of cardiovascular and metabolic anomalies. Data revealed 95.32% to 96.93% precision and accuracy of analysis among samples from control and diabetic patients. Nonetheless, standardized and internationally recognized training of staff regarding accuracy, precisions, reproducible analytical methods, can induce correctness and able to produce accurate outcome, even staff working in different shifts of mornings and evenings.

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